DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740-3835

December 7, 2016
Re: Food Contact Notification FCN 001686
Final Letter (Revised)

Dear Dr. Wu:

This letter is in reference to the notification for the food contact substance and use described as follows:

Food Contact Substance (FCS)
1,2-Benzisothiazolin-3-one (CAS Reg. No. 2634-33-5)

Notifier
Shanghai Miken Biotech Co., Ltd

Manufacturer/Supplier
Shanghai Miken Biotech Co., Ltd

Intended Use
As a biocide in uncured liquid rubber latex used to manufacture repeat-use rubber gloves intended for use in contact with all types of food, except for use in contact with infant formula and human milk (see Limitations/ Specifications).

Limitations/Specifications
For use at levels not to exceed 0.05 percent by weight of the latex solids.
The finished food contact articles will not be used in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the FCN.

This is to inform you that FCN 001686 will become effective on December 1, 2016. It will be added to the list of effective notifications, which can be accessed from the Internet in the Ingredients, Packaging & Labeling section under the Food topic of www.fda.gov.

The Agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The Agency's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to the subject FCS manufactured by Shanghai Miken Biotech Co., Ltd, and is limited to the use identified above. You should inform the Agency of any modification to the FCS, the limitations/specifications given in the notification, or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act (21 U.S.C. 342), use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(ll).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Vivian M. Gilliam -S

Digitally signed by Vivian M. Gilliam -S
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Vivian Gilliam
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Attachment (1)

Attachment 1

Definitions of Food Types and Conditions of Use for Food Contact Substances

These tables were created for easy reference for notifications relating to a food contact substance.

Table 1--Types of Raw and Processed Foods

I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
IV. Dairy products and modifications:
  A. Water-in-oil emulsions, high- or low-fat
  B. Oil-in-water emulsions, high- or low-fat.
V. Low-moisture fats and oil.
VI. Beverages:
  A. Containing up to 8 percent of alcohol.
  B. Nonalcoholic.
  C. Containing more than 8 percent alcohol.
VII. Bakery products other than those included under Types VIII or IX of this table:
  A. Moist bakery products with surface containing free fat or oil.
  B. Moist bakery products with surface containing no free fat or oil
VIII. Dry solids with the surface containing no free fat or oil (no end test required).
IX. Dry solids with the surface containing free fat or oil.

Table 2--Condition of use

A. High temperature heat-sterilized (e.g., over 212 deg. F).
B. Boiling water sterilized.
C. Hot filled or pasteurized above 150 deg. F.
D. Hot filled or pasteurized below 150 deg. F.
E. Room temperature filled and stored (no thermal treatment in the container).
F. Refrigerated storage (no thermal treatment in the container).
G. Frozen storage (no thermal treatment in the container).
H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  1. Aqueous or oil-in-water emulsion of high- or low-fat.
  2. Aqueous, high- or low-free oil or fat.
I. Irradiation
J. Cooking at temperatures exceeding 250 deg. F